



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,263	11/28/2001	Phillip Dan Cook	ISIS-4943	3783

32650 7590 08/12/2003

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
----------	--------------

1635

13

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Fi 6

Office Action Summary

Application No.

09/996,263

Applicant(s)

COOK ET AL.

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of Application/Amendment/Claims

1. Applicant's response filed May 27, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 26, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. Applicant's original IDS filed February 2, 2002 was considered, and form 1449 signed and returned in the previous Office communication. Said IDS contained several references that were not considered for the following reasons. Reference "BK" was not considered as it was not in proper format. References "BO" and "FH" were not provided. Reference "GS" is a duplicate. Translations of references "HY", "IR", and "IV" were not provided.

Applicants have resubmitted the entire PTO-1449 reference listing that corrects the improper reference to "BK". It has now been considered, and page 4 of PTO-1449 that lists reference "BK" is included herewith. The status of the remaining references not considered previously (i.e. discussed above) remains unchanged.

Response to Arguments

4. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and is repeated for the same reasons of record as set forth in the Office action mailed March 26, 2003.

The invention of the above listed claims is drawn to a mixed sequence oligonucleotide or oligonucleotide analog including more than one 2'-modified 2'-deoxyfuranosyl moiety wherein said modification comprises substitution by halo, azido, amino, alkoxy, thioalkoxy, alkylamino, alkyl, and wherein one of said 2'-modified 2'-deoxyfuranosyl moieties is different from another of said 2'-modified 2'-deoxyfuranosyl moieties, or wherein one of the two different moieties is alkoxy, which may be methoxy, or an alkyl group which may comprise a straight or branched chain alkyl, wherein said alkyl may contain unsaturation, and said nucleotide sequence that is nuclease resistant.

The claims were rejected previously on the grounds that the while the instant claims requiring at least two different 2'-modifications is broadly encompassed by the originally filed disclosure, which requires at least one such modification, it does not provide specific written support for oligos that must be comprised of more than one such modifications selected from halo, azido, amino, alkoxy, thioalkoxy, alkylamino, and alkyl, because such oligos containing more than one different 2'-modifications are not referenced or explicitly disclosed.

Applicants have traversed the rejection above on the grounds that the specification does disclose such oligonucleotides containing more than one of the disclosed modifications. In support, applicants have pointed to page 64, lines 5-8, which discloses an oligo containing both 2'-deoxy-2'-methylthio and 2'-deoxy-2'-O-methyl substituents. Applicants imply that this disclosure alone provides sufficient written support for the breadth of the claim language.

This position is not considered convincing. While it is true that the oligo indicated by applicants provides one example of a nucleotide that falls within the scope of the claim language, this one example does not provide support for the full and remaining scope of applicants' claimed oligos. Applicants have not pointed to any other oligos other than that provided for in applicants' response that fall within the claimed scope, and the specification does not appear to teach or fairly suggest any other oligos that contain at least two different modifications from the list of modifications claimed, aside from the one pointed to by applicants.

For example, while the oligo pointed out by applicants provide support for oligos containing 2'-deoxy-2'-methylthio and 2'-deoxy-2'-O-methyl, substituents, there is no apparent indication or teaching in the instant or any previous specification to which priority is claimed that would lead one to make any other oligo that contains at least at least two modifications chosen from the group of halo, azido, amino, alkoxy, or, alkylamino, substitutions as claimed herein. Although the specification provides examples of oligonucleotides that contain one such substitution, there is no teaching, beyond that for the oligo containing 2'-deoxy-2'-methylthio and 2'-deoxy-2'-O-methyl, that would persuade one of skill in the art that applicant was in possession of an any other oligonucleotide containing two different modifications from the claimed list. For example, no apparent teaching exists that would lead one to make or use an

Art Unit: 1635

oligo containing both a 2'-azido and a 2'-alkylamino modification, despite applicants' amendment specifically claiming such a compound. For this reason, the rejection of record is maintained.

5. Claims 8-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. (U.S. Patent Number 5,612,215), and is repeated for the same reasons of record as set forth in the Office action mailed March 26, 2003.

Applicants have argued that the instant rejection is based on the fact that priority is not being granted back to any parent application. In applicant's opinion, since the rejection above under written description should be withdrawn, the instant rejection is thereby obviated. Applicants have further pointed to pages 52-53 of priority application serial number 07/835,932 and stated that it oligonucleotides are disclosed therein that comprise at least two different 2'-substitutions from the claimed group of substitutions. Upon inspection of said application, it is not apparent that there is any single oligonucleotide in said application that comprises two or more different modifications on the same oligo. Should applicants disagree, applicants are invited to point out with particularity by ^{col./}page and line number where exactly such an oligo is taught. In the absence of such a teaching, for reasons as outlined above, applicants are not considered to possess adequate written description for the full breadth and scope of oligonucleotides containing two or more distinct modifications, and accordingly, priority is not granted. The claims therefore stand rejected.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1635

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
August 11, 2003



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600